



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 3 August 2011

SUBJECT: Flufenacet. Amended/Final Report For Bridging Studies Supporting Registration and Postemergence Use of SC Formulation in/on Corn

PC Code: 121903

Decision No.: 448284

Petition No.: NA

Risk Assessment Type: NA

TXR No.: NA

MRID No.: 48456001

DP Barcode: 389208

Registration No.: 264-819, 264-765

Regulatory Action: Section 3 Registration

Case No.: NA

CAS No.: 142459-58-3

40 CFR: 40 CFR §180.527

Ver. Apr. 08

FROM: Amelia M. Acierto, Chemist
Risk Assessment Branch III
Health Effects Division (7509P)

A handwritten signature in black ink, appearing to read "Amelia Acierto", is positioned to the right of the "FROM:" field.

THROUGH: Stephen Funk, Senior Chemist
Risk Assessment Branch III
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A handwritten signature in black ink, appearing to read "Stephen Funk", is positioned to the right of the "THROUGH:" field.

TO: Sheila Healy, PhD, Toxicologist/Risk Assessor
Risk Assessment Branch III
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and

Maggie Rudick/Kable Davis RM 25
Herbicide Branch
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I. CONCLUSION.

The new submitted data from the bridging studies are adequate and indicate that flufenacet residues in/on corn resulting from application of the suspension concentrate (SC) formulation and

the dry flowable (DF) formulation are comparable. HED finds that the new data satisfies the requirement for additional side-by-side studies noted in DP# 372545 (10/26/2010).

The final report submitted by Bayer CropScience summarizes the results from the bridging studies conducted in 2008 and 2010 and show that sufficient data are available to support the registration and postemergence use of Define™ SC Herbicide on sweet or field corn.

II. ACTION REQUESTED.

Bayer CropScience requested to register Define™ SC Herbicide, EPA Reg. No. 264-819 (a suspension concentrate (SC) containing 480 g ai/L) for an early postemergence use on sweet and field corn. Currently, only the 60% dry flowable (DF) formulation (Define™ DF Herbicide, EPA Reg. No. 264-265) is registered for the postemergence use on sweet and field corn.

III. BACKGROUND

Bayer CropScience has previously submitted field trial data from side-by-side bridging studies to compare the residues of flufenacet in/on corn following a single spray application (in separate test plots) of Define DF and Define SC Herbicide. The field trials were conducted in Zone 5 (Rockwood, Ontario, Bagley, IA, and Delavan, WI) during the 2008 growing season. Data from corn K+CWHR, forage, grain, and stover were collected from samples harvested from the Ontario and Wisconsin trial sites. Only residues from corn forage were collected from samples harvested from the Iowa site. Based on the available data, HED recommended for registration of the SC formulation (Define™ SC Herbicide, EPA Reg. No. 264-819) pending completion of the side-by-side bridging crop field study in the Iowa field site and submission of data. In response, Bayer CropScience submitted data generated from a side-by-side field trial conducted in Lenexa, KS. HED finds the new data adequate to satisfy the deficiency in support of the registration of Define SC for postemergence use on corn.

IV. FACTS AND RATIONALE SUBMITTED IN SUPPORT OF THIS ACTION:

MRID 48456001. Miller, A.L.; Define SC and Define DF- Magnitude of the Residue in/on Corn; Bayer CropScience LP, Stilwell, KS, USA, Report No. RAFOP001-1; Document No.: M-358526-02-1; Original Report: November 06, 2009; Supplemental Report: March 22, 2011, Pages 239.

The final report summarizes four side-by-side crop field studies conducted in 2008 and 2010 on sweet and field corn. The use pattern, directions for use and sampling and analyses from the 2008 and 2010 trials are identical. Pertinent information on the trial site conditions, study use pattern and results are included below.

Study Site Information

Four corn side-by-side field trials were conducted during 2008-2010 comparing residues resulting from the application of DF and SC formulations of flufenacet. The field trials were

conducted in Zone 5 (in 2008 in Rock wood, Ontario, Bagley, IA and Delavan, WI, and in 2010 in Lenexa, KS). At each field site, the SC and DF formulations were each applied in separate plots as single broadcast applications at the target rate of 0.785 lb ai/A. The applications were made at the early postemergence stage (BBCH 15 or V5). Applications were made in volumes of 9-14 gal/A using ground equipment. Use of adjuvant was not indicated.

The actual temperature and rainfall averages were within average historical values (gathered over at least 10 years) for the residue study period. Irrigation was used to supplement rainfall as needed. The tests were conducted according to normal agricultural practices for the different regions, and information was provided on maintenance pesticides and fertilizers used at each location.

TABLE 1. Trial Site Conditions for Flufenacet in/on Corn.

Trial Identification (City, State; Year)	Trial Number	Soil characteristics				Meteorological Data ^a	
		Type	% OM	pH	CEC (meq/100 g)	Total Rainfall (in)	Temp. Range ^b °F
Rockwood, Ontario, Canada (2008)	F0001-08HA	Sandy Loam	3.4	7.5	12.4	24.46	36-77
Bagley, IA (2008)	F0002-08HA	Loam	4.3	7.2	21.8	20.19	39-83
Lenexa, KS (2010)	F0002-08HC	Silty Clay Loam	3.7	5.7	18.4	28.84	54-92
Delavan, WI (2008)	F0003-08HA	Silt Loam	2.6	6.7	12	21.77	29-83

^aData from nearest government weather station

^bInterval from month of first application to last sampling.

TABLE 2. Study Use Pattern.

Location (City, State, NAFTA Region/Year)	End-Use Product	Application Information ¹				
		Method; Timing	Volume (gal/A)	Single Rate (lb ai/A)	RTI ² (days)	Total Rate (lb ai/A)
Rockwood, Ontario, Canada Region 5 (2008)	Define SC	Broadcast spray at BBCH 15	9.7	0.794	NA	0.794
	Define DF		9.9	0.812		0.812
Bagley, IA Region 5 (2008)	Define SC	Broadcast spray at BBCH 14	14	0.776	NA	0.776
	Define DF		14	0.767		0.767
Lenexa, KS Region 5 (2010)	Define SC	Broadcast spray at BBCH 15	9.9	0.774	NA	0.774
	Define DF		9.9	0.777		0.777
Delavan, WI Region 5 (2008)	Define SC	Broadcast spray at BBCH 15	9.9	0.801	NA	0.801
	Define DF		9.9	0.799		0.799

¹ No adjuvants were used.

² RTI = Retreatment Interval.

TABLE 3. Trial Numbers and Geographical Locations		
NAFTA Growing Zones	Corn (side-by-side)	
	Submitted	Requested ^{1, 2}
		U.S.
1		
1A		
2		
3		
4		
5	3	3
5A		
5B		
6		
Total	3	3

¹IA site had only forage data and is not included in the total count of trials.

² D288564 and 288565, A. M. Acierto, 11/29, 2006

Sample Handling and Preparation

Single composite samples from the control plots and duplicate composite treated samples of sweet corn ears [kernels plus cob with husks removed (K+CWHR)], sweet corn forage, field corn forage, grain, and stover were collected from Ontario, KS and WI sites. Sweet corn ears (K+CWHR) and sweet corn forage were collected at BBCH 75-79, field corn forage were collected at BBCH 75-85, field corn grain, and stover were collected at commercial maturity at BBCH 87-89.

Samples were kept cold in the field and frozen within 4 hours of collection until shipped to Bayer Research Park (Stilwell, KS), where the samples were stored frozen until extracted and analyzed.

Analytical Methodology

The analytical method reported in DP# 372545 which has been reviewed and found adequate with some revisions by the EPA Analytical Laboratory (DP# 290377, C. Stafford, 4/0/2004).is summarized as follows: Samples were analyzed for residues of flufenacet and its metabolites using a slightly modified common moiety gas chromatographic/single ion mode (GC/SIM) method (Bayer Method No. 106406). Flufenacet and its metabolites were converted through oxidation and subsequent hydrolysis to a common analyte, 4-fluoro-*N*-methyl-benzenamine, which was removed from the matrix by steam distillation and derivatized to 4-fluoro-*N*-methylethyl benzeneamine trifluoroacetamide. Residues were then determined by GC with mass selective detector (GC/MSD) and expressed in parent equivalents. The method LOQ was 0.05 ppm for sweet corn (K+CWHR) and field corn grain and 0.10 ppm for corn forage and stover. Concurrent recoveries of flufenacet from corn are summarized in Table 4.

Storage Stability

Sample storage conditions and durations for corn samples are presented in Table 5; the maximum storage duration from harvest to analysis was 344 days (~11.5 months). Adequate data are available indicating that flufenacet is stable under frozen storage conditions for at least 20 – 28 months in wheat, corn, soybean, and turnip (DP 235485 and 235347, N. Dodd, 9/4/97). These data are adequate to support the storage conditions and durations of samples from the current field trials.

Crop Field Trials

Residue data from the corn side-by-side field trials are reported in Table 6 and summarized in Table 7. In corn harvested 75-80 days following application of the SC and the DF formulations in the side-by-side trials at rates totaling 0.794 – 0.812 lb ai/A, residues of flufenacet were <LOD to 0.128 ppm for the SC and <LOD to 0.343 ppm for the DF formulations. In general, the flufenacet residues in corn treated with the SC formulation were either equal or less than those treated with the DF formulation.

TABLE 4. Summary of Concurrent Recoveries of Flufenacet from Corn.				
Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± Std. Dev. (%)
Sweet Corn (K+CWHR) (1)	0.05	11	104, 104, 104, 103, 108, 106, 93, 94, 108, 108, 98	103 ± 5
Sweet Corn Forage (2)	0.10	3	106, 108, 98	103 ± 6
Field Corn Forage (3)	0.10	13	102, 104, 102, 103, 108, 110, 97, 98, 105, 105, 108, 113, 96	104 ± 5
	0.50	3	105, 105, 105	105 ± 0
Field Corn Grain (4)	0.05	11	104, 103, 104, 103, 108, 109, 99, 102, 107, 104, 96	104 ± 4
Field Corn Stover (5)	0.10	9	103, 106, 112, 107, 117, 115, 100, 105, 97	107 ± 7
	0.05	2	109, 108	108 ± 1

LODs (1) = 0.008, (2) = .0.014, (3) = 0.014, (4) = 0.005, (5) = 0.018

Untreated Controls were all below the reported LODs.

TABLE 5. Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration ^a	Interval of Demonstrated Storage Stability
Field Corn Forage	<0	344 days (~11.5 months)	857 days (28.6 mos.) ^b
Field Corn Grain	<0	301 days (~10 months)	857 days (28.6 mos.) ^b
Field Corn Stover	<0	305 (~10.2 months)	857 days (28.6 mos.) ^b

^a Interval from harvest to extraction.

^b DP 235485 and 235347, N. Dodd, 9/4/97.

TABLE 6. Residue Data from Crop Field Trials with Flufenacet ¹						
Trial ID (City, State; Year)	Zone	Variety	Formulation	Total Rate (lb ai/A)	PHI (days)	Flufenacet Residues (ppm) ¹
Sweet Corn (K+CWHR) (LOD = 0.008 ppm)						
Rockwood, Ontario, Canada (2008)	5	Dekalb DKC35-15	480 g/L SC	0.794	76	<LOD, <LOD
			60% DF	0.812	76	<LOD, <LOD
Delavan, WI (2008)	5	Dekalb DKC51-39	480 g/L SC	0.801	75	<LOD, <LOD
			60% DF	0.799	75	<LOD, <LOD
Lenexa, KS (2010)	5	DKC61-72	480 g/L SC	0.774	70	<LOD, <LOD
			60% DF	0.777	70	<LOD, <LOD
Sweet Corn Forage						
Rockwood, Ontario, Canada	5	Dekalb DKC35-15	480 g/L SC	0.794	76	0.032, 0.022 (0.027)
			60% DF	0.812	76	<LOD, <LOD
Delavan, WI	5	Dekalb DKC51-39	480 g/L SC	0.801	75	0.047, 0.118 (0.082)
			60% DF	0.799	75	0.343, 0.132 (0.237)
Lenexa, KS (2010)	5	DKC61-72	480 g/L SC	0.774	70	0.048, 0.063 (0.055)
			60% DF	0.777	70	0.039, 0.040 (0.040)
Field Corn Forage (LOD = 0.014 ppm)						
Rockwood, Ontario, Canada	5	Dekalb DKC35-15	480 g/L SC	0.794	80	0.022, 0.020 (0.021)
			60% DF	0.812	80	<LOD, <LOD
Bagley, IA	5	33H27	480 g/L SC	0.776	75	0.128, 0.114 (0.121)
			60% DF	0.767	75	0.121, 0.058 (0.089)
Delavan, WI	5	Dekalb DKC51-39	480 g/L SC	0.801	78	0.107, 0.019 (0.063)
			60% DF	0.799	78	0.041, 0.312 (0.176)
Lenexa, KS (2010)	5	DKC61-72	480 g/L SC	0.774	79	0.064, 0.063 (0.063)
			60% DF	0.777	79	0.044, 0.048 (0.045)
Field Corn Grain (LOD = 0.005 ppm)						
Rockwood, Ontario, Canada	5	Dekalb DKC35-15	480 g/L SC	0.794	121	<LOD, <LOD
			60% DF	0.812	121	<LOD, <LOD
Delavan, WI	5	Dekalb DKC51-39	480 g/L SC	0.801	123	<LOD, <LOD
			60% DF	0.799	123	<LOD, <LOD
Lenexa, KS (2010)	5	DKC61-72	480 g/L SC	0.774	118	<LOD, <LOD
			60% DF	0.777	118	<LOD, <LOD
Field Corn Stover (LOD = 0.018 ppm)						
Rockwood, Ontario, Canada	5	Dekalb DKC35-15	480 g/L SC	0.794	121	0.028, 0.032 (0.030)
			60% DF	0.812	121	<LOD, <LOD
Delavan, WI	5	Dekalb DKC51-39	480 g/L SC	0.801	123	0.027, 0.031 (0.029)
			60% DF	0.799	123	0.050, 0.042 (0.046)
Lenexa, KS (2010)	5	DKC61-72	480 g/L SC	0.774	118	0.030, <LOD (0.024)
			60% DF	0.777	118	<LOD, <LOD

¹ All trials except KS were reviewed previously (D373545, A. Acierto, 10/26/2010). The information is repeated here for completeness.

TABLE 7. Summary of Residue Data from Corn Treated with Flufenacet.										
Commodity	Formulation	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) ¹						
				n	Min.	Max.	HAFT ²	Median (STMdR)	Mean (STMR)	Std. Dev.
Sweet Corn (K+CWHR)	SC	0.774-0.801	70-76	6	<0.05	<0.05	<0.05	<0.05	<0.05	NA ⁴
	DF	0.767-0.812	70-76	6	<0.05	<0.05	<0.05	<0.05	<0.05	NA
Sweet Corn Forage	SC	0.774-0.801	70-76	6	<0.10	0.118	<0.10	<0.10	<0.10	0.034
	DF	0.767-0.812	70-76	6	<0.10	0.343	0.237	<0.10	<0.10	0.129
Field Corn Forage	SC	0.774-0.801	75-80	8	<0.10	0.128	0.121	<0.10	<0.10	0.045
	DF	0.767-0.812	75-80	8	<0.10	0.312	0.176	<0.10	<0.10	0.100
Field Corn Grain	SC	0.774-0.801	118-123	6	<0.05	<0.05	<0.05	<0.05	<0.05	NA
	DF	0.767-0.812	118-123	6	<0.05	<0.05	<0.05	<0.05	<0.05	NA
Stover (Fodder)	SC	0.774-0.801	118-123	6	<0.10	<0.10	<0.10	<0.10	<0.10	0.005
	DF	0.767-0.812	118-123	6	<0.10	<0.10	<0.10	<0.10	<0.10	0.019

¹ Based on total residue values² HAFT = Highest Average Field Trial.³ NA = not applicable

REFERENCES

DP Barcode: 372543

Subject: Flufenacet. Bridging Studies Supporting Postemergence Application Uses of SC Formulation. Summary of Analytical Chemistry and Residue Data.

From: Amelia M. Acierto

To: Hope Johnson/Jim Tompkins, RM 25

Dated: 10/26/2010

MRIDs: 47930801

DP Barcodes: 288564 and 288565

Subject: Flufenacet. Registration for Use on Field Corn, Sweet Corn, Soybeans, Wheat, and Grass Grown for Seed. Summary of Analytical Chemistry and Residue Data. Petition Number: 6F04631

From: Amelia M. Acierto

To: Tobi L. Colvin-Snyder/Jim Tompkins, RM 25

Dated: 11/29/2006

MRIDs: 45012401-45012408, 45796116, 45806001, 45806002, 46005301

DP Barcodes: 235485 and 235347

Subject: PP#6F04631 - Thiafluamide (FOE 5043) on Field Corn and Soybeans. Storage Stability Data and Rotational Crop Data. Amendment dated 1/2/97.

From: N. Dodd

To: P. Errico/J Tompkins

Dated: 9/4/97

MRID(s): 44228701 and 44253100-44253103

DOCUMENT TRACKING

RDI: Amelia M. Acierto (8/3/2011); ChemTeam (8/5/2011); Stephen Funk (8/8/2011)

Petition Number: NA

DP#: 389208

PC Code: 121903